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Cause of Death Within 30 Days of Percutaneous Coronary Intervention in an Era of Mandatory Outcome Reporting

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Objectives This study sought to ascertain causes of death and the incidence of percutaneous coronary intervention (PCI)-related mortality within 30 days.

Background Public reporting of 30-day mortality after PCI without clearly identifying the cause may result in operator risk avoidance and affect hospital reputation and reimbursements. Death certificates, utilized by previous reports, have poor correlation with actual cause of death and may be inadequate for public reporting.

Methods All patients who died within 30 days of a PCI from January 2009 to April 2011 at a tertiary care center were included. Causes of death were identified through detailed chart review using Academic Research Consortium consensus guidelines and compared with reported death certificates. The causes of death were divided into cardiac and noncardiac and PCI and non–PCI-related categories.

Results Of the 4,078 PCI, 81 deaths (2%) occurred within 30 days. Of these, 58% died of cardiac and 42% of noncardiac causes. However, only 42% of 30-day deaths were attributed to PCI-related complications. Patients with non–PCI-related, compared with PCI-related, death presented with a higher incidence of cardiogenic shock (15 of 47 [32%] vs. 2 of 34 [6%]; $p < 0.01$) and cardiac arrest (19 of 47 [40%] vs. 1 of 34 [3%]; $p < 0.01$). Death certificates had only 58% accuracy (95% confidence interval: 45% to 72%) for classifying patients as experiencing cardiac versus noncardiac death.

Conclusions Less than one-half of 30-day deaths are attributed to a PCI-related complication. Death certificates are inaccurate and do not report PCI-related deaths, which may represent a better marker of PCI quality. (J Am Coll Cardiol 2013;62:409–15) © 2013 by the American College of Cardiology Foundation

Public reporting of outcomes after percutaneous coronary intervention (PCI) is likely to be made standard practice as advocated by the Centers for Medicare and Medicaid Services (1). Implementation of this policy will lead to several important consequences. First, Medicare and Medicaid reimbursements for healthcare professionals and institutions will be based on their outcomes (2). Second, mandatory reporting and disclosure of these data will affect the credibility and reputation of a healthcare provider, hopefully helping patients to make informed decisions about their healthcare choices (3). Finally, analysis of the outcomes data will be useful in determining appropriateness and hence cost-effectiveness of performing these procedures (4).

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Whereas publicly reported outcomes could be considered surrogate markers for healthcare quality, thus far, such disclosures have resulted in mixed reactions from healthcare providers (5–7). In New York and Massachusetts where PCI outcomes were first publicly reported, a strong selection bias toward avoidance of PCI in high-risk patients was subsequently described (8,9). Because of these potentially adverse consequences, many have advocated the importance

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Abbreviations and Acronyms

ARC = Academic Research Consortium
CI = confidence interval
GI = gastrointestinal
PCI = percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction

of reporting risk-adjusted outcomes, which try to take into account the severity of underlying illnesses (10–14). However, PCI-associated deaths are exceedingly rare, and although risk models are helpful for the majority of patients, their ability to predict the risk of death in very small subgroups (such as PCI patients at very high risk of death) is poor (11). Moreover, the majority of these risk scores were derived from mortality data obtained through death certificates, which are often inaccurate in precisely identifying the cause of death (15–17). Another limitation is lack of data on PCI versus non–PCI-related mortality, which may be a better measure of operator performance and PCI quality. For these reasons, we conducted a detailed chart review to identify the causes of 30-day post-PCI deaths employing standard definitions from globally recognized Academic Research Consortium (ARC) consensus guidelines (18,19).

Methods

Study population. All patients who underwent PCI from January 2009 to April 2011 at a single tertiary care center were identified through the institutional review board–approved institutional PCI registry. Baseline characteristics, cardiac history and risk factors, medications, other chronic medical illnesses, and angiographic and procedural data were prospectively obtained and recorded. Thirty-day deaths after PCI were identified after querying the Social Security Death Index. Circumstances surrounding death such as the decision to withdraw care and site of death were obtained. Medical charts were retrospectively reviewed for cause of death together by 2 clinicians (B.A. and M.H.S.) using standard ARC definitions to prevent any bias. Cause of death by chart review was compared with death certificates when available.

Definitions. Cardiogenic shock on presentation was defined as systolic blood pressure persistently <90 mm Hg or the need for inotropic support or intra-aortic balloon pumping to maintain systolic blood pressure >90 mm Hg, in the presence of adequate left ventricular filling pressure and systemic hypoperfusion (18). Neurological dysfunction was defined as Glasgow Coma Scale score <9 or unresponsiveness to any stimuli with absence of brain stem reflexes (in cases were the Glasgow Coma Scale was not checked).

Cause of death was defined as the precipitating factor for the patient's demise, independent of the presenting medical problem on admission (20). There were 19 deaths after initial discharge of whom 8 died after readmission. An attempt to obtain information regarding 11 out-of-hospital deaths was made through a nurse phone call to the patients' families. Of these, no record could be obtained, and the families could not be reached for 5 patients.

The causes of death were divided into cardiac- and noncardiac-related and PCI- and non–PCI-related categories. Cardiac death was defined as any death due to proximate cardiac cause (such as myocardial infarction, low output failure, or fatal arrhythmia), unwitnessed death, death from unknown cause, and all procedure-related deaths, including those related to concomitant treatment. Noncardiac causes were divided into respiratory, infectious, neurological, gastrointestinal (GI), renal and hemato-oncological categories (Table 1). All deaths were considered cardiac unless an unequivocal noncardiac cause could be established. In cases without reasonable clinical evidence toward one or the other, death was determined noncardiac only if stable cardiac pump function was determined by pulmonary artery catheterization.

PCI-related death was defined as death from complication of procedure such as vascular dissection, aneurysm, perforation, bleeding, renal failure, and definite or probable stent thrombosis. Stent thrombosis was defined as "definite" after angiographic confirmation or "probable" in case of any unexplained death within 30 days or any myocardial infarction that was related to documented acute ischemia in the territory of the implanted stent (18). Any bleeding was considered PCI-related if it occurred within 72 h of the procedure, and death from such bleeding was labeled as a complication of PCI (21).

Statistical analysis. PCI and non–PCI-related deaths were compared with regard to demographics, past medical history, presenting history, indication for procedure, and the

Table 1 Definitions of Noncardiac Causes of Death

Cause of Death	Definition
Infectious	Death from severe sepsis or septic shock as defined by the Society of Critical Care Medicine/American College of Chest Physicians consensus conference guidelines (19).
Neurological*	Death due to anoxic brain injury prior to PCI, cerebrovascular accident, or brain death from any cause.
Pulmonary	Death after worsening respiratory status due to primary lung pathology including acute respiratory distress syndrome.
Gastrointestinal	Death from massive gastrointestinal bleeding, as complication of liver disease, cancer, or gastrointestinal perforation not related to dual antiplatelet therapy.
Hemato-oncological	Death from life-threatening hemorrhage (except gastrointestinal and intracranial hemorrhage) or due to an advanced cancer, its complication, or withdrawal of care due to concerns regarding poor prognosis associated with cancer.
Renal†	Death due to complication of renal failure such as fluid overload, acidosis, and electrolyte disturbances.

*In patients with cardiac arrest, death was adjudicated to be neurological only if neurological dysfunction was documented prior to the start of percutaneous coronary intervention (PCI). In addition, the patient was also required to have a successful PCI with restoration of stable cardiac pump function as determined by either a pulmonary artery catheterization or lack of inotropic support. In equivocal cases or if no such data were available, cause of death was considered to be cardiac. †Excluding patients with contrast-induced nephropathy from iodinated contrast administered during PCI.

site of death. Continuous variables were presented as mean ± SD or median with interquartile range, and categorical variables were presented as percentage affected. Fisher exact test for categorical variables and Wilcoxon rank order test for continuous variables were used to compare differences in categories. Accuracy, sensitivity, and specificity of death certificates for classifying patients as experiencing cardiac versus noncardiac death were calculated after assuming chart review diagnosis as the gold standard. All tests were 2-tailed and a p value <0.05 was considered significant.

Results

A total of 4,078 PCI (including emergent, urgent, elective, and salvage) were performed from January 2009 to April 2011. All-cause mortality within 30 days of PCI was 2% (n = 81), and a cause of death could be established in 76 patients. Death records were not available for 5 patients who died after hospital discharge. Forty-seven patients (58%) died from cardiac and 34 (42%) from noncardiac causes (Fig. 1). Fifty-three patients presented with cardiogenic shock and underwent PCI, of these, 17 (32%) died within 30 days. Similarly, mortality for patients presenting with ST-segment elevation myocardial infarction (STEMI) and undergoing PCI was 7% (37 of 535 patients), whereas that for patients presenting with cardiac arrest was 41% (20 of 49 patients).

Of the noncardiac causes of death, complications of infection such as septic shock or severe sepsis were most common. About one-half of these had evidence of active infection prior to PCI (as demonstrated by a positive blood culture within 72 h of PCI). Death due to a neurological cause was the next most prevalent noncardiac cause (Fig. 1). The majority of these were from withdrawal of care after anoxic brain injury, which had likely occurred prior to PCI as a result of cardiac arrest or shock.

Of the cardiac deaths, 34 patients died from PCI-related complications and 13 from non–PCI-related cardiac complications mainly related to pump dysfunction. The majority of PCI-related deaths were attributed to probable stent thrombosis (Fig. 2). Four patients died from fatal bleeding within 72 h of PCI with 2 cases of intracranial hemorrhage and 1 case each of massive GI bleeding and retroperitoneal hemorrhage. Lastly, 3 patients died from coronary dissection, and 2 died from complications of renal failure attributed to iodinated contrast administered with the procedure. Both patients had documented stable renal function prior to PCI.

Baseline and angiographic characteristics of PCI and non–PCI-related deaths (including noncardiac) are shown in Table 2. Both groups were comparable in terms of baseline demographics and pre-existing cardiac risk factors. However, patients who died from a non–PCI-related death presented more often with cardiogenic shock ($p < 0.01$) or cardiac arrest ($p < 0.01$) and had a higher prevalence of New York Heart Association functional class IV heart failure ($p < 0.01$) prior to hospitalization (Table 2). In addition, non–PCI-related deaths occurred more often during index admission than did PCI-related deaths ($p < 0.01$) (Fig. 3).

Death certificates were available in 53 patients. There was poor correlation between death certificates and chart review for classifying death into cardiac versus noncardiac death. When compared with chart review, death certificates had a sensitivity of 69% (95% confidence interval [CI]: 52% to

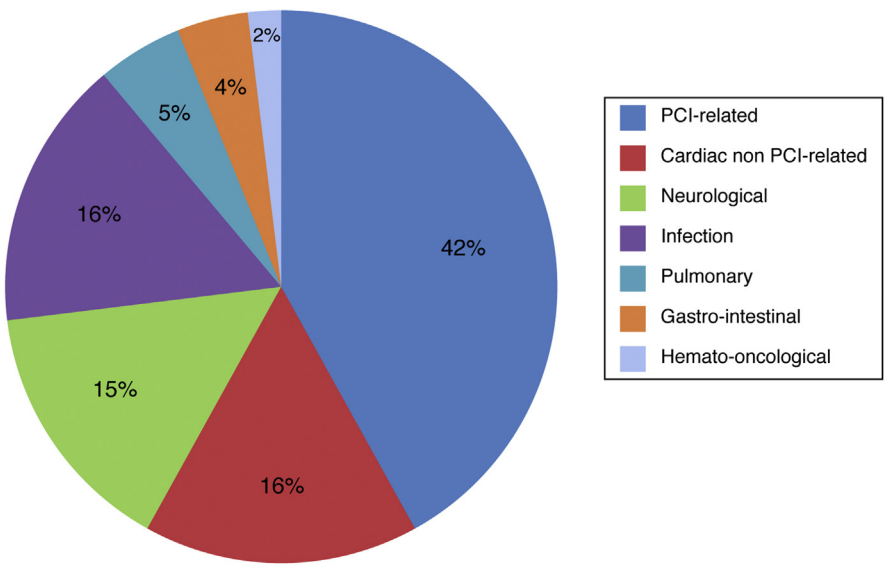

Figure 1 Etiology of 30-Day Mortality After PCI Based on Chart Review

Etiology of death (in percentage) divided into percutaneous coronary intervention (PCI)-related, cardiac non–PCI-related, neurological, infection, pulmonary, gastrointestinal, and hemato-oncological causes.

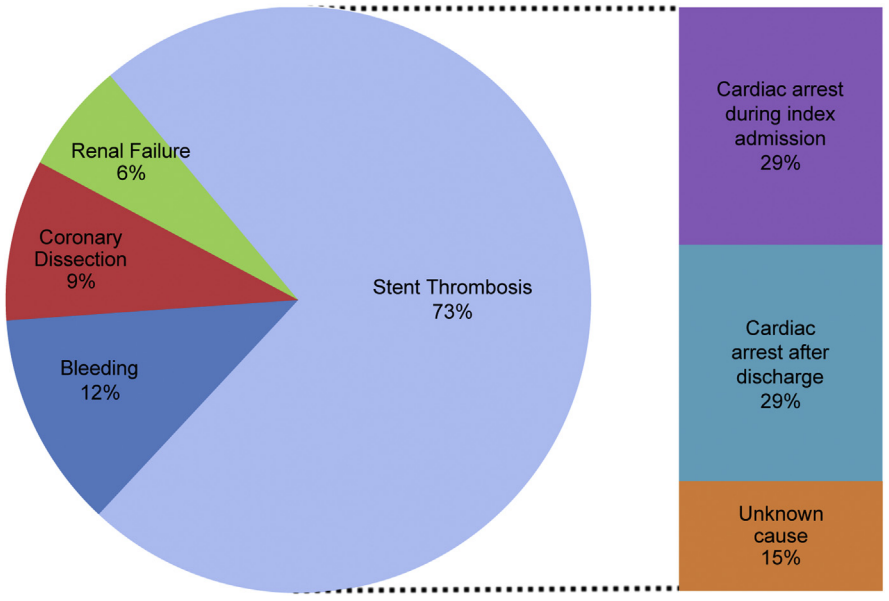

Figure 2 **Etiology of 30-Day Mortality Due to PCI-Related Complications Based on Chart Review**

Specific etiology of death (in percentage) from complication of percutaneous coronary interventions (PCI) divided into bleeding, renal failure, coronary dissection, and stent thrombosis. Death from stent thrombosis is further divided into death from cardiac arrest during admission, cardiac arrest after discharge, and unknown cause.

86%), specificity of 46% (95% CI: 26% to 66%), and an accuracy of 58% (95% CI: 45% to 72%) (Fig. 4).

Discussion

This is the first report in the past decade identifying etiology of death within the critical 30-day period after a PCI from a thorough chart review and using standard ARC guidelines. In our cohort, cardiac causes contributed to 58% of all deaths after PCI, and only 42% were attributed to complications associated with the procedure. Even this was perhaps an overestimation because all unexplained deaths within 30 days of PCI were considered probable stent thrombosis in this analysis. This is in contrast to previously reported data using death certificates where a much higher proportion of deaths were attributed to cardiac- and PCI-related complications (15,22–24). The highest-risk patients (cardiogenic shock and cardiac arrest) who may potentially experience risk avoidance rarely died from a PCI-related complication. In addition, a poor correlation between cause of death determined by chart review and that reported by death certificates was observed. These results highlight the limitations of 30-day mortality reporting when death certificates are used and emphasize the need for identifying PCI-related deaths rather than cardiac deaths alone.

Mortality is an outcome measure that is most likely to influence reimbursements and the public reputation of an institution. Therefore, it is important to classify causes of death into categories that truly reflect a physician and an institution's competence and acts as an indicator of performance. Most PCI and acute coronary syndrome outcome studies classify deaths as from either cardiac or noncardiac causes rather than PCI- or non–PCI-related causes. Such classification may be misleading as institutional reporting of low cardiac death rates may be a result of risk avoidance (refusing PCI in high-risk patients such as those with STEMI, cardiogenic shock, or cardiac arrest) or a result of referral of such patients to different centers (6,7,25). We propose classifying post-PCI deaths as PCI- or non–PCI-related, which better represents quality of PCI and operator performance.

The overall mortality after PCI for a given provider is greatly influenced by the severity of a patient's illness and presentation. This is currently determined by several risk scores, but there remain concerns among interventionalists regarding the validity of these to accurately predict mortality after PCI (26). Because the expected in-hospital mortality after PCI is very low, this concern is especially relevant to the patients at the highest risk of death (27). Lack of trust in the current risk prediction models has led to avoidance of high-risk cases by clinicians in centers where outcome reporting was made mandatory. This was evident from the outcomes data published from the New York State PCI registry, which revealed that in-hospital mortality after PCI had declined from 0.90% in 1997 (28) to 0.58% in 2003 (29), a reduction of 36%. Although this might be superficially interpreted as due to a significant quality improvement, closer analysis revealed a simultaneous trend toward avoidance of PCI in patients presenting with cardiogenic shock (8). Similar results were observed in data from the Massachusetts PCI registry when outcome reporting became mandatory in that state (27). A "compassionate use" variable was proposed to account for

Table 2 Patient Characteristics According to Etiology of Death by Chart Review

	PCI-Related Death (n = 34)	Non–PCI-Related Death (n = 47)	p Value
Baseline characteristics and cardiac risk factors			
Age, yrs	69 ± 14	71 ± 11	0.43
Male	19 (56)	28 (60)	0.82
Previous myocardial infarction	20 (59)	32 (68)	0.48
Previous percutaneous coronary intervention	14 (41)	15 (32)	0.48
Previous coronary artery bypass graft	3 (9)	9 (19)	0.23
Diabetes mellitus	14 (41)	24 (51)	0.50
History of renal failure	5 (15)	11 (23)	0.41
Current smoker	4 (12)	11 (23)	0.25
Peripheral vascular disease	8 (24)	9 (19)	0.78
Cardiac characteristics at admission			
Ejection fraction	39 ± 15	36 ± 15	0.58
STEMI	13 (38)	24 (51)	0.27
Non–STEMI	5 (15)	14 (30)	0.18
Unstable angina	5 (15)	2 (4)	0.12
Cardiogenic shock	2 (6)	15 (32)	<0.01
Cardiac arrest	1 (3)	19 (40)	<0.01
Other comorbid conditions			
History of stroke/transient ischemic attack	5 (15)	11 (23)	0.41
Neurological dysfunction	3 (9)	14 (30)	0.03
Infection pre-procedure	1 (3)	6 (13)	0.23
Dementia	4 (12)	0 (0)	0.03
Outside hospital transfer	20 (59)	25 (53)	0.66
New York Heart Association functional class			
I	1 (3)	3 (6)	0.64
II	4 (12)	2 (4)	0.23
III	11 (32)	3 (6)	<0.01
IV	18 (53)	39 (83)	<0.01
Number of diseased vessels			
1	22 (65)	31 (66)	1.00
2	8 (24)	11 (23)	1.00
3	4 (12)	5 (11)	1.00
Stent placed	31 (91)	44 (94)	0.69
Use of intra-aortic balloon pump	8 (24)	12 (26)	1.00
Creatinine pre-procedure, mg/dl	1.3 (0.9–1.6)	1.2 (1.0–1.7)	0.79
Hemoglobin pre-procedure, g/dl	11 ± 2	11 ± 3	0.33

Values are mean ± SD, n (%), or median (interquartile range).
PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction.

patients with highest risk, whereas other investigators proposed that perhaps patients presenting in cardiogenic shock and cardiac arrest should be omitted from mandatory reporting (10). According to Massachusetts Data Analysis Center definitions, 22% (n = 18) of our patients who died met the compassionate use criteria; however, of these, only 4 had PCI-related mortality. Among the remaining 78% (n = 63), 52% (33 of 63) died of non–PCI-related mortality, highlighting the current limitation of excluding only those patients meeting the compassionate use definition.

Of the patients who died in our cohort, 58% (47 of 81 patients) presented with STEMI, cardiogenic shock, or cardiac arrest. This highlights the high-risk nature of many patients undergoing PCI who could potentially be considered emergent or salvage. Emergent procedures are not currently excluded from public reporting, and the current NCDR (National Cardiovascular Data Registry) definition of salvage PCI would not incorporate many of these patients (21). In our cohort, the majority of these patients did not die of a PCI-related complication, perhaps indicating that such a presentation should not be a deterrent to PCI if otherwise indicated. Although these patients contribute significantly toward overall mortality, they are also individuals who are likely to benefit the most from PCI (30,31). Whereas some investigators have suggested excluding such patients from public reporting, using PCI- and non–PCI-related outcomes will allow public transparency yet avoid risk avoidance in these high-risk patients.

The main limitation of previous publications assessing PCI-associated mortality has been the sole reliance on death certificates that are well documented to be susceptible to serious biases and are often inaccurate (32–36). They often fail to capture other acute medical events during the course

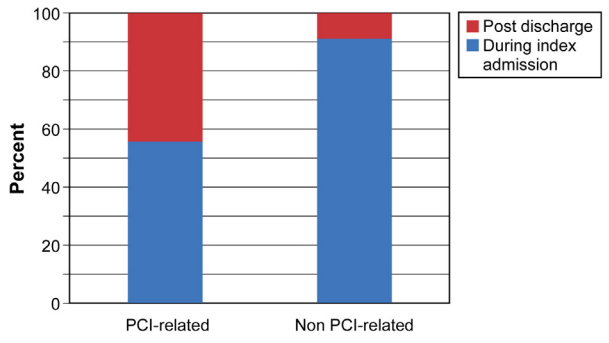

Figure 3 Site of Death Among PCI and Non–PCI-Related Categories

Site of death in percutaneous coronary intervention (PCI) and non–PCI-related death categories divided into those during index admission or after discharge (in percentage). Non–PCI-related death occurred more often during index admission than PCI-related deaths did ($p < 0.01$).

of the hospital stay, which ultimately contributed to the death of the patient, thereby often mislabeling the etiology of death (37). Physicians often do not recall the cause of death and may confuse underlying cause of death with mechanism of death (20). In addition, such data may suffer from biases of ascertainment, whereby knowledge of a patient's prior medical conditions may affect physicians' interpretations of cause of death. For example, a patient's presentation with a myocardial infarction may bias a physician to label subsequent death as cardiac, even when it may not have been so. Similar to others' findings, death certificates had low sensitivity and specificity in our analysis. Therefore, it is reasonable to conclude that death certificates are an inaccurate representation of cause of death and hence should not be used for outcome reporting. There is no current consensus on the process of accurately determining

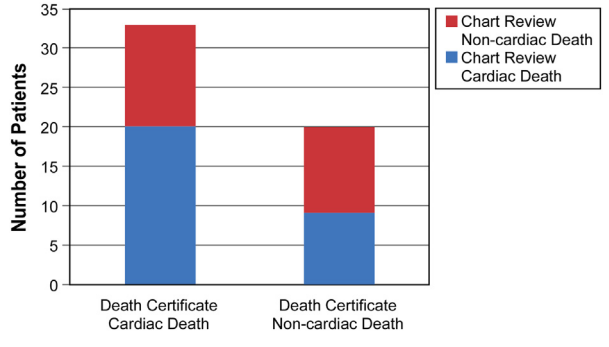

Figure 4 Cause of Death as Designated on Death Certificates Compared With Chart Review

Cause of death as designated on death certificates is divided into cardiac and noncardiac categories. These categories are further divided into those correlating with cause of death as determined by chart review. Death certificates had a sensitivity of 69% (95% confidence interval [CI]: 52% to 86%), specificity of 46% (95% CI: 26% to 66%), and an accuracy of 58% (95% CI: 45% to 72%).

the cause of death, and questions on how the etiology of death should be established and who will ascertain it (hospital/healthcare professional performing the procedure or an independent committee) remain unanswered.

There are also other issues related to public reporting. Currently, there is no consensus on adjudicating death from anoxic brain injury after cardiac arrest into cardiac versus noncardiac death, especially if the patient underwent a successful PCI. Similarly, PCI-related complications such as bleeding or contrast-induced nephropathy may represent patient frailty rather than a direct complication of PCI. In our cohort, 4 patients had fatal bleeding; of these, only 1 was related to access site complication. Excluding the 3 patients with GI and intracranial bleeding would result in a lower incidence of PCI-related death. Furthermore, in many cases, a single cause of death cannot be identified due to ongoing multiorgan failure. Lastly, current public health reporting does not reward institutions that successfully treat high-risk patients who were refused previously nor report institutions that refuse PCI when it is indicated.

Study limitations. This is a single-center study and data from a tertiary referral hospital may not apply across other centers. Our study has a small sample size; however, our findings appear to be consistent with other studies that have assessed the accuracy of death certificates for determining cause of death. A conservative approach to adjudication of death as cardiac was made, and actual rates of cardiac death after PCI may be lower. We acknowledge the lack of standard definitions for several of the noncardiac causes of death across different registries, but we have made an attempt to use standard or common practice definitions wherever possible. All outside hospital cardiac arrests and deaths were considered as stent thrombosis and a PCI-related mortality; however, it is possible that a portion of these patients died from arrhythmias or other cardiac causes not related to PCI. Lastly, despite making every effort to be objective, unintentional errors in determining the exact cause of death may have occurred.

Conclusions

Public reporting of PCI outcomes will allow transparency, help patients make informed decisions, and may be linked to reimbursements. However, in its current form, this may lead to risk avoidance and worse outcomes in high-risk patients. Classification of deaths into PCI-related and non–PCI-related may be a better marker of operator performance and quality of procedure. Death certificates have limitations and are not ideal for public health reporting.

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